

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: NOVARTIS and PAR
ANTITRUST LITIGATION

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: No. 2:19-mc-00149
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OPINION

Joseph F. Leeson, Jr.
United States District Judge

November 5, 2019

I. INTRODUCTION

The Purchaser Plaintiffs, Retailer Plaintiffs, and End-Payor Plaintiffs (collectively, “Plaintiffs”) are part of an antitrust litigation originating in the Southern District of New York alleging Defendant Novartis conspired with fellow Defendant Par to ensure Par delayed the launch of a generic drug competing with Novartis. *See In re Novartis & Par Antitrust Litig.*, No. 1:18-cv-04361-AKH (S.D.N.Y.). Currently, Plaintiffs are in the midst of a discovery dispute with non-party Alembic Pharmaceutical, Inc. over the production of subpoenaed documents. Alembic does not object to the entire subpoena, only Requests One, Two, Three, Four, Five, Seven, Twelve, and Thirteen. Presently pending before this Court is Plaintiffs’ Federal Rule of Civil Procedure 45(f) motion to transfer this discovery dispute to the Southern District of New York, or, in the alternative, to compel Alembic to produce the documents subpoenaed. For the reasons set forth below, Plaintiffs’ motion to transfer is denied and their motion to compel is granted in part and denied in part.

II. BACKGROUND

In the underlying case, Plaintiffs allege Novartis entered into an anticompetitive agreement with Par whereby Par agreed to delay the launch of its generic version of Exforge, a hypertension drug, until September 30, 2014, in exchange for Novartis' agreement not to launch its authorized generic version of Exforge until Par's generic had been on the market for six months. Plaintiffs further assert this agreement created a bottleneck that prevented other generic applicants, such as Alembic, from obtaining Federal Drug Administration approval to sell Exforge until the exclusivity's expiration as companies would need to wait to obtain approval to launch their version of generic Exforge. Plaintiffs allege this delay injured them because generic Exforge prices would have been lower if more generics were available for sale on the market.

Plaintiffs served Alembic a subpoena to produce documents on November 21, 2018, including:

1. All Paragraph IV Certification Letters relating to any of the Patents.
2. All documents concerning the potential market entry of Authorized Generic Exforge or Authorized General Exforge HCT or lack thereof, including documents concerning the actual and/or forecasted sale of Authorized Generic Exforge, or Authorized Generic Exforge HCT, and including the impact of a potential market entry of Authorized Generic Exforge or Authorized Generic Exforge HCT or lack thereof on unit and/or dollar sales, gross and net revenues, profits, and/or unit process of Exforge, Generic Exforge, Generic Exforge HCT, Exforge HCT, Authorized Generic Exforge, or Authorized Generic Exforge HCT.
3. All documents concerning Your Generic Exforge or Generic Exforge HCT ANDA, and any other company's Generic Exforge or Generic Exforge HCT ANDA, including but not limited to the ANDAs themselves, the ANDA FDA correspondence logs, all supplements and amendments thereto, all communications to and from the FDA, Par, or Novartis (including memorializations of oral communications such as telephone contact reports) concerning such ANDAs, and all internal documents concerning any such Generic Exforge or Generic Exforge HCT ANDA(s).
4. All documents concerning Your, Par's, Novartis's or any other company's actual, proposed, or contemplated plans for launching Generic Exforge or Generic Exforge

HCT, including the following: (i) launch timelines, new product launch meeting minutes, projections, and forecasts, including any assumptions used; (ii) schedules; (iii) launch updates, action items from new product launch meetings, and launch team meeting minutes; (iv) “at-risk” launch analysis and discussions; (v) manufacturing forecasts; (vi) sourcing of active and inactive ingredients (including communications with any suppliers); (vii) exhibit batches, scale up, validation, building and maintenance of commercial quantities, and/or manufacture, sale, transfer, or destruction of same; and (viii) public statements (including statements to investors or courts) and competitive intelligence.

5. All documents concerning any regulatory, legal, technical, manufacturing, or other issues other reasons why You or any other Generic Exforge ANDA filer could or could not or would or would not commercial launch a Generic version of Exforge prior to September 30, 2014, including but not limited to
 - a. All documents concerning the manufacturing sites, facilities, equipment, and other resources proposed, contemplated, or actually used in the development, regulatory approval, scale-up, validation, commercial manufacturing, and launch of Generic Exforge.
 - b. All documents concerning CGMP, inspections, manufacturing, quality control, or quality assurance regarding any manufacturing sites, facilities, or equipment proposed, contemplated, or actually used in the development, regulatory approval, scale-up, validation, commercial manufacturing, and launch of Generic Exforge.
 - c. All documents relating to potential or actual suppliers of active or inactive ingredients, container/closure systems, labeling, tooling, or other vendors of products or services for Generic Exforge, including, but not limited, communications with any such company(ies); order and cancellation of orders; invoices and payments; contracts (including amendments and supplements thereto); drafts of contracts; compliance with contracts; disputes; settlements of disputes; forecasts; projection; manufacturing ability; supply requirements; production schedules; supply schedules, product marketing; product launch dates; internal memoranda; emails; meeting agendas and minutes; transcripts of conversations; and drug master files.
 - d. All documents relating to actual and theoretical manufacturing capacity and the rate limiters on that capacity, including any shortages in raw materials; manufacturing sites and/or equipment, or other rate limiters for Your Generic Exforge Product.
 - e. Documents sufficient to show the amount of inventory expressed in terms of weeks or months on hand of inventory that You had of Generic Exforge at the time of anticipated launch and/or at the time You actually launched Your Generic Exforge product.

- f. Documents sufficient to show batch sizes, manufacturing process, throughput times per batch, and manufacturing rates for Your Generic Exforge product.

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- 7. ESI in a tab-, comma-, or semicolon-delimited ASCII flat text file or similar electronic format from September 1, 2014, to the present sufficient to identify sales of Generic Exforge and Exforge HCT in transaction-by-transaction format, as follows:
 - a. All direct sales/invoice transaction (as well as any discounts or any other price adjustments or offsets contained in the transaction data) including the following fields: (i) price or dollar amount, (ii) source of the transaction price, (iii) number of units sold; (iv) returned or otherwise affected by the transaction; (v) unit of measure; (vi) date of transaction; (vii) information sufficient to identify the type of transaction (e.g. a sale, a return, a discount, etc.); (viii) NDC; (ix) UPC; (x) SKI; (xi) product description; (xii) product form; (xiii) product strength; (xiv) package size in extended units per package; (xv) bill-to and ship-to customer name; (xvi) customer number; (xvii) customer address; (xviii) customer class of trade code and the description of that code (all such customer information being provided for both the bill-to customer and the ship-to customer); and (xix) the customer's parent company (if the data identify a subsidiary, corporate affiliate, division, satellite office, distribution center, warehouse, or the like).
 - b. All data concerning chargeback, rebates, discounts, and other consideration given or accrued, including the following fields: (i) each transaction, including the date thereof; (ii) the name and address of, all unique codes or identifiers for, the Person, firm, corporation, or other business entity whom You paid, or on whose behalf you accrued, the chargeback, rebate, discount and/or other consideration; (iii) the name and address of, and all unique codes or identifiers for, the Persons firms, corporations, or other business entities that made the purchases in respect of which You paid or accrued the chargeback, rebate, discount or other consideration; (iv) the sales, or group of sales, upon which the rebate, discount or other consideration is based, including (aa) the number of units of the participate product sold, by package size, SKU, UPC, NDC, and any and all other unique codes or other identifiers for each sale or other transaction; (bb) the bill-to customer; (cc) the ship-to customer; (dd) the dates of the sales, or group of sales; (ee) the invoice amount in dollars for the sales or group of sales; (ff) the amount of the chargeback, rebate, discount or other consideration paid or accrued; and (gg) the contract, promise, agreement, or other basis upon which the chargeback, rebate, discount, or other consideration is calculated.
 - c. All administrative fee transactions, including: (i) fee amount paid, (ii) date of payment, (iii) date or date range of sales concerning the fee that was paid; (v) information sufficient to identify the type of administrative fee (if applicable); (vi)

customer number; (vii) customer address; and (viii) customer class of trade code and description of that code.

- d. Any other paid or accrued discounts, rebates, chargebacks, billbacks, unit adjustments, price adjustments, shelf-stock price adjustments, returns, third-party returns, error corrections, free goods, nominally priced goods, and all other transaction types not reflected in the proceeding subsections (a. through c. above), whether created or maintained daily, monthly, quarterly, or at some other interval.
- e. The complete documentation for all items a. through d. above including: (i) lookup tables, (ii) data dictionaries, (iii) list of fields; (iv) descriptions of information contained in those fields (e.g. field lengths, formats, etc.); (v) descriptions of any codes use in ay fields (such as class of trade designations, etc.); (vi) a separate product list, including NDC, SKU, UPC, product description, and package size; (vii) a separate table that lists, for each “bill-to customer” and “ship-to customer,” the customer number, parent customer number, customer group number, customer identity, contact information, address, and class of trade (e.g. SIC code); (viii) a separate table listing and defining each transaction code, abbreviation, or other field or entry code, and indicating: (1) whether quantity values for each transaction type should be included in calculating net quantity sold, or should be ignored because they do not affect the net quantity sold; and (2) how negative unit and dollar values should be treated in calculating net quantities and dollar amounts; (ix) all datasets and calculations used: (1) to determine accrued rebates and/or chargebacks; and/or (2) to periodically reconcile accrued rebates and/or chargebacks with actual rebates and/or chargebacks, (x) return and/or exchange policies; and (xi) payment terms.

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- 12. All documents concerning the projected and actual gross and net revenues, returns, profits, margins, contribution, costs (including initial and ongoing research and development costs) and expenses from the sale of Exforge, Exforge HCT, Generic Exforge, or Generic Exforge HCT in the United States (including Puerto Rico and the territories of the United States) from January 1, 2009 to the present.
- 13. As pertaining to Generic Exforge and Generic Exforge HCT, each forecasted and/or actual financial statement, budget, profit, and loss statement, cost report, profitability report, balance sheet, account reconciliation, or other financial report regularly prepared by or for You on a periodic basis from the time of filing of Your Generic Exforge or Generic Exforge HCT ANDA(s) until the present day.

Pl. Mot., Ex. 1, ECF No. 1.

Plaintiffs requested Alembic to respond to the subpoena in their Philadelphia office “or such place as agreed upon by counsel by any form of mail” on December 12, 2018. *Id.*

However, Alembic objected on the basis it is a sales and marketing subsidiary of Alembic India and that Alembic India has exclusive custody and control of all Exforge related documents, with the exception being its generic Exforge sales data. Alembic refused to produce their sales data, citing confidentiality concerns. After several failed attempts to meet and confer to rectify the issue, Plaintiffs filed a motion to compel in the Southern District of New York. In a letter to Plaintiffs' counsel, Alembic objected to Plaintiffs' filing in the Southern District of New York because of Federal Rule of Civil Procedure 45(d)(2)(B)(i). *See* Pl. Mot., Ex. 9. Plaintiffs withdrew their motion in the Southern District of New York, and refiled their motion in this Court.

III. STANDARD OF REVIEW

A. Motion to Transfer

Under Federal Rule of Civil Procedure 45(f), “[w]hen the court where compliance is required did not issue the subpoena, it may transfer a motion under this rule to the issuing court if the person subject to the subpoena consents or if the court finds exceptional circumstances.” The proponent of transfer bears the burden of showing exceptional circumstances. Fed. R. Civ. P. 45 Advisory Committee Notes on 2013 Amendments. The Southern District of New York, not the Eastern District of Pennsylvania, issued the subpoena which we are asked to review. Despite this fact, Alembic does not consent to transfer of the motion to compel to the Southern District of New York.

The Advisory Committee Notes to Rule 45 provide when determining whether exceptional circumstances exist, the “prime concern should be avoiding burdens on local nonparties subject to subpoenas, and it should not be assumed that the issuing court is in a superior position to resolve subpoena-related motions.” *Id.* But the Advisory Committee Notes

further explain transfer may be warranted “in order to avoid disrupting the issuing court’s management of the underlying litigation.” *Id.* The Advisory Committee Notes provide the examples of when the issuing court has already ruled on the same issues presented by the motion or the same issues are likely to arise in discovery in many districts. *Id.* In such instances, transfer to the issuing court is warranted to ensure uniformity of result.

Apart from avoiding disruption in the issuing court’s management of the underlying litigation, the court may also consider the complexity of the underlying litigation. *See Meijer Inc. v. Ranbaxy Inc.*, No. 17-91, 2017 WL 2591937, at *3 (E.D. Pa. Jun. 15, 2017). Transfer is appropriate only if the interests favoring transfer outweigh the interests of the local nonparty served with the subpoena in obtaining a local resolution of the motion. Fed. R. Civ. P. 45 Advisory Committee Notes on 2013 Amendments.

B. Motion to Compel

Federal Rule of Civil Procedure 26 limits the scope of discovery in civil suits to “any nonprivileged matter that is relevant to any party’s claim or defense.” Fed. R. Civ. P. 26(b)(1). “Although the scope of discovery under the Federal Rules is unquestionably broad, this right is not unlimited and may be circumscribed.” *In re Domestic Drywall Antitrust Litigation*, 300 F.R.D. 234, 238 (E.D. Pa. 2014) (quoting *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999)); *Frank v. Honeywell Int’l, Inc.*, No. 15-00172, 2015 WL 4770965, at *4 (E.D. Pa. Aug. 12, 2015) (stating that “[c]ourts have significant discretion when resolving discovery disputes”).

Rule 26(c)(1) can be invoked to shield the target of a discovery request from “annoyance, embarrassment, oppression, or undue burden or expense.” Fed. R. Civ. P. 26(c)(1). When discovery is sought from a non-party, “[b]roader restrictions may be necessary to prevent a non-

party from suffering harassment or inconvenience.” *See Avago Techs. U.S., Inc. v. IPtronics, Inc.*, 309 F.R.D. 294, 297 (E.D. Pa. 2015) (citing *Frank*, 2015 WL 4770965 at *2).

Federal Rule of Civil Procedure 45 correspondingly protects non-parties from subpoenas to testify. “A non-party may seek from the court protection from discovery via the overlapping and interrelated provisions of both Rules 26 and 45.” *Frank*, 2015 WL 4770965 at *2 (quoting *In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2012 WL 298480, at *39 (E.D. Pa. Jan. 31, 2012)). “A subpoena served under Rule 45 must fall within the scope of proper discovery under Rule 26(b)(1).” *Saller*, 2016 WL 8716270 at *3. After the subpoenaing party demonstrates the information it seeks is relevant to a party’s claim or defense, the person objecting to the subpoena has the burden to establish grounds, under Rule 45, for the court to quash the subpoena. *Id.* Rule 45 directs that a court must quash or modify a subpoena that “(i) fails to allow a reasonable time to comply; (ii) requires a person to comply beyond the geographical limits specified in Rule 45 (c); (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; (iv) subjects a person to undue burden.” Fed. R. Civ. P. 45(d)(3)(A). The party seeking Rule 45 protection has a higher burden of “demonstrating that an enumerated need for quashing the subpoena exists.” *Saller*, 2016 WL 8716270 at *3. Rule 26(c) is less stringent, requiring the objecting party to show “good cause.” *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986).

Once a requesting party has shown the information they seek is relevant under Rule 26(b), a court may balance the “potential hardship to the party subject to the subpoena” against the requesting party’s need. *Avago Techs*, 309 F.R.D. at 297 (quoting *Truswal Sys. Corp. v. Hydro-Air Eng’g, Inc.*, 813 F.2d 1207, 1210 (Fed. Cir. 1987)). A court balancing undue hardship against need for the requested information may consider multiple factors, including the “(1)

relevance of the requested materials, (2) the party's need for the documents, (3) the breadth of the request, (4) the time period covered by the request, (5) the particularity with which the documents are described, (6) the burden imposed, and (7) the recipient's status as a non-party.” *Frank*, 2015 WL 4770965 at *2.

IV. ANALYSIS

A. Motion to Transfer

Contrary to Plaintiffs' argument, this Court is well equipped to handle the motion. The Court does not find there are exceptional circumstances to warrant transfer to the Southern District of New York. Alembic notes in their brief it is not contesting the relevance of the documents subpoenaed by Plaintiffs, but whether Alembic controls such documents. Accordingly, the risk of disparate outcomes is minimal because this is an issue specific to Alembic and not the parties involved.

The Court finds the cases Plaintiffs cited, such as *United States of America ex rel. Simpson v. Bayer Corp.*, No. 16-207, 2016 WL 7239892 (E.D. Pa. Dec. 15, 2016), are inapposite. In *Bayer*, the case lasted for ten years and the plaintiff served ten subpoenas to nonparties across the country. Furthermore, in *Meijer*, 2017 WL 2591937, at *3, the court issued a detailed scheduling order, including more than thirty specific deadlines. Plaintiffs fail to establish such unique circumstances in this instance.

Lastly, the interests favoring transfer do not outweigh the interests of the nonparty served with the subpoena. Plaintiffs originally filed this motion in the Southern District of New York, withdrew their motion, and refiled in this District. However, Alembic opposes such a transfer and favors a local resolution of the motion. It is notable to this Court that Plaintiffs chose this District, but yet wish to now transfer the motion. In Plaintiffs' motion, they seek for compliance

in Philadelphia. *See Avago Techs.*, 309 F.R.D. at 296 (stating “[o]n timely motion, the court for the district where compliance is required must quash or modify a subpoena”) (quoting Fed. R. Civ. P. 45(d)(3)(A)). Thus, Plaintiffs’ argument for transfer is inconsistent with the facts. If transferred, Alembic would need to relitigate this issue in the Southern District of New York. This Court considers Alembic’s arguments persuasive. Resultantly, Plaintiffs motion to transfer is denied.

B. Motion to Compel

Plaintiffs organize their motion to compel in five sections: (1) Alembic’s sales data, (2) regulatory data for generic Exforge, (3) manufacturing and launch documents for generic Exforge, (4) forecasting and projection documents for generic Exforge, and (5) Paragraph IV Certification notice letters. Alembic does not object to the entire subpoena, only Requests One, Two, Three, Four, Five, Seven, Twelve, and Thirteen. Alembic states it should not be compelled to produce these documents; however, Alembic submits if this Court were to order it to produce the documents, Plaintiffs should bear the costs and Alembic’s confidentiality must be protected. For the following reasons, Plaintiffs’ motion to compel is granted in part and denied in part.

i. Requests Two, Seven, Twelve, and Thirteen

In Requests Two, Seven, Twelve, and Thirteen of the subpoena, Plaintiffs request Alembic’s generic Exforge projection, sales, and financial data to establish damages due to the price differential. For the following reasons, Plaintiffs’ motion to compel Alembic to produce Requests Two, Seven, Twelve, and Thirteen of the subpoena is granted.

Plaintiffs correctly note sales data pertaining to generic brands in antitrust cases in routinely produced. *See In re Wellbutrin XL Antitrust Litigation*, No. 08-2431, 2011 WL 3563385, at *15 (E.D. Pa. Aug. 11, 2011) (stating utilizing the “before and after” methodology

which produces a damages estimate that is based on deriving a benchmark for generic prices in the “but for world” based on the actual experience for branded and generic prices after entry); *Direct Purchaser Class Plaintiffs v. Apotex Corp.*, No. 16-62492, 2017 WL 4230124 (S.D. Fl. May 15, 2017) (ordering non-party to produce documents that sought sales data for generic Celebrex to allow for expert pricing absent the defendant’s anticompetitive conduct); *In re Namenda Direct Purchaser Antitrust Litigation*, No. 25-7488, 2017 WL 4700367, at *3 (S.D.N.Y. Oct. 19, 2017) (ordering non-party to produce transactional sales data pertaining to a generic drug in an antitrust issue).

Alembic is concerned about its confidentiality, the expenses to produce such documents, and Plaintiffs’ overbroad requests. These concerns will be addressed later in the opinion. However, it is clear to the Court these sales and forecasting documents are essential in determining potential damages. Without such documents, Plaintiffs would fail to adequately determine damages. Plaintiffs’ theory revolves around a conspiracy to prohibit the entry of generic Exforge into the market which kept prices artificially high. Sales and forecasting documents would be helpful in determining the extent of damages.

Alembic has a sales office in the United States. Thus, it should not be implausible that a sales office possesses sales and forecasting documents. A competent sales office would have forecasting documents, impact of market entry analyses, sales data, projected and actual gross profits and revenue, budgets, financial statements, and other relevant sales documents necessary for the profitability of the product. This type of request is neither extraordinary or burdensome given the circumstances. *See In re Wellbutrin*, 2011 WL 3563385, at *15; *see also In re Namenda*, 2017 WL 4700367, at *3. Products such as Exforge are not just simply released to the public, there is a process of sales analysis to determine the feasibility. As such, both the sales and

forecasting documents are relevant. Therefore, Plaintiffs' motion to compel regarding Request Two, Seven, Twelve, and Thirteen of their subpoena is granted.

ii. Requests One, Three, Four, and Five

Alembic objects to Plaintiffs' Requests One, Three, Four, and Five because it claims it is a sales subsidiary of Alembic India with no possession or control of such documents. Alembic states it is two levels removed from Alembic India with Alembic Holdings controlling Alembic and then Alembic Holdings being controlled by Alembic India. Plaintiffs categorize the documents as regulatory data for generic Exforge, manufacturing and launch documents for Exforge, projection documents for generic Exforge, Paragraph IV Certification notice letters. For the following reasons, Plaintiffs' Requests' One, Three, Four, and Five of the subpoena is denied.

The court can compel a corporate entity that is deemed to be in "control" of documents to produce those documents, even if they are also in the possession and control of a nonparty. *Novartis Pharm. Corp. v. Eon Labs Mfg., Inc.*, 206 F.R.D. 392, 395 (D.Del. 2002). "Control is defined as the legal right to obtain the documents required on demand." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 233 F.R.D. 143, 145 (D.Del. 2005) (citing *Gerling Int'l Ins. Co. v. Comm'r*, 839 F.2d 131, 140 (3d Cir. 1988)). The court has declined to apply a broader definition of "control" that would also include an inquiry into the practical ability of the subpoenaed party to obtain documents. *Id.* at 146. Although control is often found when a parent corporation is requested to produce documents of a wholly-owned subsidiary, separate and distinct corporate identities are not readily disregarded, "except in rare circumstances justifying the application of the alter ego doctrine to pierce the corporate veil of the subsidiary." *Novartis*, 206 F.R.D. at 395 (finding no control when two corporate entities were not "so intertwined as to

render meaningless their separate corporate identities”). The district court has discretion whether to quash or modify a subpoena. *See Wedgewood Vill. Pharmacy, Inc. v. United States*, 421 F.3d 263, 268 n.5 (3d Cir. 2005); *Connaught Labs., Inc. v. SmithKline Beecham P.L.C.*, 7 F. Supp. 2d 477, 480 (D.Del. 1998).

Courts should also consider what information is available to the requesting party from other sources. *See* 9A CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2463.1, at 501–06 (3d ed. 2008). To that end, the requesting party should be able to explain why it cannot obtain the same information, or comparable information that would also satisfy its needs, from one of the parties to the litigation—or, in appropriate cases, from other third parties that would be more logical targets for the subpoena. *Virginia Dept. of Corrections v. Jordan*, 921 F.3d 180, 189 (4th Cir. 2019).

The bulk of the instant dispute revolves around whether Alembic has “control” over documents or information that is in the possession, custody, or control of Alembic. *Power Integrations* is instructive on this issue. In *Power Integrations*, the court quashed a subpoena that was served on LGE–USA, a non-party American company, after finding that LGE–USA had no control over documents it would be required to obtain from LGE–Korea, its foreign parent company. LGE–USA and LGE–Korea had “little more than a vendor relationship;” LGE–USA did not utilize the information requested in the subpoena in the normal course of its business; and another entity, LGE–Alabama, was responsible for service and maintenance issues related to LGE–Korea’s products. *Power Integrations*, 233 F.R.D. at 145–46. The court concluded that the corporate relationship between LGE–USA and LGE–Korea did not present the “rare circumstances” to justify disregarding the separate and distinct corporate identity of LGE–USA. *Id.* at 144–45.

Here, Alembic successfully shows it does not have control or can otherwise produce the remaining documents Plaintiffs wish to compel. Alembic, a subsidiary two levels removed from its parent company, does not meet the definition of control as elicited by the Third Circuit. *Power Integrations, Inc.*, 233 F.R.D. at 145 (citing *Gerling Int'l*, 839 F.2d at 140). Contrary to Plaintiffs' argument, courts in the Third Circuit have declined a broader definition of control that would include an inquiry into the practical ability of the subpoenaed party to obtain documents. *Id.* at 146. Absent such precedent, the Court cannot compel Alembic to inquire to its parent company, Alembic India, to produce documents.

Plaintiffs failed to show how regulatory data, Request Three in their subpoena, for generic Exforge would be in the control of Alembic, a sales office. It is unlikely that a subsidiary, two-levels removed from the parent company, would control or possess regulatory files. The regulations guiding generic Exforge are irrelevant to sales data of generic Exforge. Alembic focuses on sales of generic Exforge, not the regulations for the drug. As such, Plaintiffs' motion to compel Alembic to produce regulatory data, Request Three in the subpoena, is denied.

Furthermore, Plaintiffs failed to show how manufacturing and launch documents pertaining to generic Exforge, Request Five in the subpoena, are controlled by Alembic and, thus, can be produced. Alembic is a sales office, it is unlikely they have control over documents that pertain to manufacturing and the launch date of generic Exforge. Decisions such as the logistics on manufacturing generic Exforge or when generic Exforge would be available to the public are outside the decisions of a sales office. Accordingly, Plaintiffs' motion to compel Alembic to produce manufacturing and launch documents pertaining to generic Exforge, Request Five, in the subpoena, is denied.

Next, Plaintiffs failed to show how projection documents, Request Four in the subpoena, can be compelled by Alembic, a sales office. As noted, Alembic is two-levels removed from its parent company. This two-level removal from the parent company is significant as it is the parent company which determines the course of business for subsidiaries, such as Alembic. Details such as projection are beyond the scope of sales. Plaintiffs failed to elaborate how Alembic is in possession or control of these documents as determined by the Third Circuit. Therefore, Plaintiffs' motion to compel Alembic to produce projection documents, Request Four in the subpoena, is denied.

For Plaintiffs' last request, Request One, they failed to show how Paragraph IV Certification notice letters, Request One in the subpoena, can be compelled. Plaintiffs failed to establish how this document, while being in the control of Alembic's parent company, can be controlled by Alembic pursuant to *Gerling International*. The burden to compel Alembic to produce documents not within its control, including having Plaintiffs admit knowing the location of these documents, outweighs any benefit. Therefore, Plaintiffs' motion to compel Alembic to produce any Paragraph IV Certification notice letters, Request One in the subpoena is denied.

In denying Plaintiffs' Requests One, Three, Four, and Five, the Court is guided by the holding in *Power Integrations*. Similar to *Power Integrations*, Alembic has no control over the documents requested it would be required to obtain from its foreign parent company, and Alembic does not utilize the documents requested in the subpoenas because it is a sales office compared to a parent company responsible for manufacturing pharmaceuticals. Resultantly, analogous to *Power Integrations*, Plaintiffs fail to present the rare circumstances to justify the piercing of the separate and distinct corporate identities between Alembic and Alembic India.

Plaintiffs rely upon two cases that are inapposite. First, Plaintiffs rely upon *Ferber v. Sharp Electronics Corp.*, No. 84-3105, 1984 WL 912479, at *3 (S.D.N.Y. Nov 28, 1984), in which the court ultimately granted the motion to compel because of the sufficiently intimate relationship where the subsidiary and parent company worked closely similar to an integrated operation. Next, Plaintiffs rely on *Cooper Indus., Inc. v. British Aerospace, Inc.*, 102 F.R.D. 918, 920 (S.D.N.Y. 1984), where the issue pertained to production by a defendant. In this instance, this is a subpoena to a non-party in which the non-party is not significantly intertwined with the parent company as it a sales operation two-levels removed. Most importantly, however, Plaintiffs cited cases from the Southern District of New York located in the Second Circuit. These cases are merely persuasive, not controlling, in the Third Circuit as compared to *Gerling International*, which is controlling.

Lastly, Alembic adroitly notes an alternative means for Plaintiffs to secure these documents. The United States and the Republic of India are parties to the Taking of Evidence Abroad in Civil or Commercial Matters. Plaintiffs failed to brief this Court on this alternative path. Thus, it appears, Plaintiffs have a path to secure the documents and are not prevented from securing the documents. Plaintiffs, rather than use an intermediary, can go directly to the source of the documents, Alembic India. Consequently, Plaintiffs' Requests One, Three, Four, and Five of the subpoena are denied.

iii. Alembic's objections of breadth, timeframe, and particularity

Alembic objects to Plaintiffs' subpoena due to its breadth, timeframe, and particularity. Plaintiffs counter stating their requests are not burdensome. For the following reasons, this Court will limit the time frame of production from January 1, 2016, to the present for Requests Seven,

Twelve, and Thirteen, and permit Alembic to provide summaries of materials due to the breadth of the requests for Requests Two, Seven, Twelve, and Thirteen.

The breadth of Plaintiffs requests are extensive as Plaintiffs have numerous subparts in their requests. For example, Request Seven consists of five subparts, each with different subsections Alembic must respond to. While Plaintiffs' requests are particular, any particularity is outweighed by the breadth of the requests. Due to the breadth and particularity, Alembic would have been unduly burdened in producing these documents. Consequently, this Court will permit Alembic to summarize documents in order to limit its burden and costs.

The time period covered by the requests, with the exception of Request Two, is too broad and unduly burdensome for Alembic. Request Seven begins September 1, 2014, and Request Twelve begins January 1, 2009. Requests Two and Thirteen do not have timeframes. These time frames are burdensome on Alembic due to their broad nature. The breadth of the requests, combined with the broad time frame, compounds the burden for Alembic, a non-party, to produce. As Requests Seven, Twelve, and Thirteen pertain to documents while Alembic sold Exforge, the time frame should be limited in order for Alembic not to be burdened. *See Composition Roofers Union Local 30 Welfare Trust Fund v. Graveley Roofing Enterprises, Inc.*, 160 F.R.D. 70, 73 (E.D. Pa. 1995) (holding a subpoena with a time period of twenty months is not unduly burdensome). As Request Two pertains to the preparation of Exforge before it was sold, a time frame limitation is not applicable due to the specificity.

Accordingly, the time period in which Alembic shall respond to Requests Seven, Twelve, and Thirteen is January 1, 2016, to the present and Alembic may, to limit its burden, provide summaries of their documents due to the breadth of Plaintiffs' requests.

iv. Confidentiality of Alembic's sales documents

Alembic requests if the Court were to order production of the documents that the documents should be redacted to prevent the disclosure of their customer names. Plaintiffs counter stating the customer names are necessary to allow Plaintiffs to calculate the prices paid to class members. Now that the Court has ruled Alembic must produce certain sales documents, it must also determine whether those documents should be redacted as Alembic requests. For the following reasons, the documents produced by Alembic will be subject to the Stipulated Protected Order issued by the Southern District of New York with the added protection of having only the parties outside counsel analyze documents deemed "Highly Confidential." The Stipulated Protective Order is, in pertinent part, as follows:

"Highly Confidential Material" shall mean any information that the Designating Party believes in good faith to be subject to federal, state, or foreign data protection or privacy laws or other privacy obligations Highly Confidential Material may include (but is not limited to) nonpublic, highly sensitive information related to (a) pricing (including but not limited to credits, discounts, returns, allowances, rebates, and chargebacks); (b) projected future sales, volumes, profits, revenue, and costs; (c) claims and reimbursement data; (d) distribution agreements with third parties, including wholesalers; (e) transaction data; (f) information protected by data privacy; (g) information related to litigation or to settlement of litigation or negotiations thereof; (h) information relating to research, development, and testing of, or production or plans for, a Party's past, existing or proposed future products; (i) information relating to the processes apparatus, or analytical techniques used by a Party or Non-Party in its present or proposed commercial production of such products; (j) information relating to compliance with product safety or other governmental regulation; (k) information relating to pending or abandoned patent applications that have not been made available to the public; (l) personnel files or other highly sensitive or personal identifying information; (m) communications regarding any Highly Confidential Material; (n) information related to a Designating Party's financial performance, projections, and planning, and (o) other materials that current trade secrets.

. . . .

Disclosure of Highly Confidential Materials. Unless otherwise ordered by the Court or permitted in writing by the Designating Party, Highly Confidential Materials

may be disclosed, summarized, characterized, or otherwise communication or made available only to:

- a. the Court, its secretaries, clerks, law clerks, and other support staff;
- b. Outside Counsel (as defined Paragraph 9(b) above), to the extent such persons' duties and responsibilities require access to Highly Confidential Material;
- c. up to five (5) in-house legal personnel for each non-designating Party, names to be provided under separate cover, as well as the secretarial and clerical employees of each Party who work regularly with in-house legal personnel for sole purpose of assisting with this Action. Should there be a change in the in-house legal personnel of a Party who may view material designated as Highly Confidential, that Party shall notify all others Parties in writing, either email or hand delivery, no fewer than five (5) days before providing the new in-house personnel with access to Highly Confidential Material;
- d. Court Reporters (as defined in Paragraph 9(d) above);
- e. Experts (as defined in Paragraph 9(e) above); and subject to all of the restrictions and conditions set forth in that paragraph.
- f. any mediators engaged by the Parties, and their support staff;
- g. any person that counsel for a Party has a good-faith basis to believe prepared, received, reviewed or had knowledge of the specific Highly Confidential Material prior to its production in this Action;
- h. any person designated as a Rule 30(b)(6) witness by the Designating Party who is testifying regarding the subject matter of the Highly Confidential Material.

In re Novartis, No. 1:18-cv-04361-AKH, ECF No. 95.

An analysis of other decisions from federal district courts establishes producing sales documents under “Attorney’s Eyes Only” is not out of the ordinary. *See Apotex Corp.*, 2017 WL 4230124, at *5 (ordering non-party produce generic drug sales documents under protective order, including documents its deems highly confidential for “Attorney’s Eyes Only”); *Covey Oil v. Continental Oil Co.*, 340 F.2d 993 (10th Cir. 1965) (ordering production of documents only available to counsel and independent certificated public accountants for “Attorney’s Eyes Only”); *Verisign, Inc. v. XYZ.com, LLC*, Case No. 15-175, 2015 WL 7960976 (D. Del. Dec. 4, 2015) (ordering production of confidential financial and sales information to competitor under “Attorney’s Eyes Only” designation).

Apotex Corp. is informative on this issue. In *Apotex Corp.*, the plaintiffs subpoenaed generic drug sales data from non-party Apotex in order to establish damages in an antitrust action alleging Pfizer delayed the entry of a generic drug to keep prices artificially high. *Apotex Corp.*, 2017 WL 4230124, at *1-3. Apotex objected to the subpoena due to confidentiality because the generic drug market is based upon product pricing, service, and supply. *Id.* at 3. The court determined the sales data was essential in determining damages in the relevant antitrust action, and ordered Apotex to produce the documents. *Id.* at 5. However, the court noted if Apotex were to produce documents deemed “Highly Confidential,” then it could designate those documents under “Attorney’s Eyes Only.” *Id.*

Here, there are similar circumstances to the facts presented in *Apotex Corp.* Similar to *Apotex Corp.*, where the plaintiffs subpoenaed a non-party for sales documents to calculate damages in a generic drug antitrust action; in this instance, Plaintiffs subpoenaed Alembic to secure documents in order to estimate damages. These documents are essential to determine alleged damages suffered by the Plaintiffs. While the Court understands the concerns of Alembic, it does not share in their pessimism. However, the Court believes the current Stipulated Protective Order is insufficient to protect the confidentiality of Alembic as Plaintiffs employees could have access to material which could compromise the pricing structure of generic Exforge. Thus, similar to *Apotex Corp.*, this Court will allow the outside attorneys only, not in-house counsel, to access material deemed Highly Confidential. This is to avoid any appearance of impropriety.

v. Costs of producing Alembic’s sales documents

Alembic requests if this Court were to order it to produce document to Plaintiffs, that Plaintiffs should bear the costs of producing the documents. Plaintiffs counter on the basis

Alembic failed to provide the Court with its estimated costs. Despite the scant briefing on this issue by the parties, this Court will deny Alembic's requests for reasonable costs, as follows.

Under Rule 45(d)(3)(C)(ii), Alembic is entitled to "compensation for time expended and expenses incurred in complying with the subpoena[]." *In re Domestic Drywall Antitrust Litigation*, 300 F.R.D. at 250 (citing *Cohen v. City of New York*, 255 F.R.D. 110, 126 (S.D.N.Y. 2008)). However, Alembic, prior to the Court issuing the award, must provide evidence to support their assertion of what the actual costs of compliance will be. *E.E.O.C. v. Kronos Inc.*, 694 F.3d 351, 372 (3d Cir. 2012); *see also United States v. Friedman*, 532 F.2d 928, 937 (3d Cir. 1976) (stating a party should be required to produce evidence of the expense likely to be incurred in compliance with the summons). Alembic has failed to produce evidence of their reasonable costs of production.

Consequently, Alembic cannot be compensated for time expended and expenses incurred for complying with the subpoena. This Court will not grant Alembic *carte blanche* to cover the costs of their production. It was incumbent upon Alembic to provide this Court of evidence of their costs, even a reasonable estimate would have sufficed. Alembic failed to do so. Thus, Alembic's request to cover the costs of their production is denied.

V. CONCLUSION

Plaintiffs' motion to transfer is denied. Plaintiffs' motion to compel is granted in part and denied in part because Alembic established it does not possess or control over certain documents Plaintiffs requested.

A separate order follows.

BY THE COURT:

/s/ Joseph F. Leeson, Jr.
JOSEPH F. LEESON, JR.
United States District Judge